Attorney's Docket No. 3764.P142

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Wouter Rhonda	Examiner: Benton, Jason
Application No. 09/749,144	Art Unit: 3747
Filed: December 27, 2000	Confirmation No.: 4762
For: VESSEL ENLARGEMENT BY ARTERIOGENIC FACTOR DELIVERY	

APPEAL BRIEF

Mail Stop Appeal Brief - Patent
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellant submits the following Appeal Brief pursuant to 37 C.F.R. §41.37(c) for consideration by the Board of Patent Appeals and Interferences. Appellant also submits herewith a check in the amount of $500.00 to cover the cost of filing the opening brief as required by 37 C.F.R. §1.17(f). Please charge any additional amount due or credit any overpayment to Deposit Account No. 02-2666.

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I. REAL PARTY IN INTEREST

Wouter Roorda, the party named in the caption, transferred his rights to the subject Application through an assignment recorded on April 24, 2001 (Reel/Frame 011747/0253) in the patent application to Advanced Cardiovascular Systems, Inc. ("ACS") of Santa Clara, California. Thus, as the owner at the time the brief is being filed, ACS is the real party in interest.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences that will affect or be affected by the outcome of this appeal.

III. STATUS OF CLAIMS

Claims 1-6, 8, 10-11, 24 and 33-37 are pending and rejected in the Application. Appellant hereby appeals the rejection of all pending claims.

IV. STATUS OF AMENDMENTS

The claims were amended in accordance with an Amendment and Response to Office Action filed September 29, 2006. The claim amendments presented at that time were entered. Accordingly, the claims stand as amended September 29, 2006.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

In one embodiment, a method is claimed. The method provides for delivering an arteriogenic factor that may structurally enlarge an existing blood vessel. See paragraph [0008]. With regard to cardiovascular vessels (see Figures 1 and 2), the method may find particular use where primary vessel 2 is impaired with occlusion 3 such as a stenotic lesion. Referring to Figures 1 and 2, occlusion 3 limits the flow of blood 4 through primary vessel 2, thus decreasing circulation and limiting the flow of blood able to reach target area 5 (e.g., an area of myocardium). See paragraph [0016]. To increase the flow of blood to the myocardium, smaller bypass vessels 7, 8, 9 treated with an arteriogenic factor may be used to increase the size of the bypass vessels. Increasing the size of bypass vessels 7, 8, 9 allows for a more complete

compensation for the lack of circulation provided through primary vessel 2 as the result of occlusion 3. See paragraph [0021]. In one embodiment, the induction of arteriogenesis includes an actual structural enlargement of the vessel involved (i.e., as opposed to a more temporary dilation). See paragraph [0022].

Claim 1 describes injuring a vessel region, the vessel region comprising a bypass vessel adjacent to a primary vessel leading to a target area for blood flow and the primary vessel having an occlusion to blood flow. With reference to Figures 1 and 2, a bypass vessel may be, for example, vessel 7, 8, or 9, with a primary vessel being vessel 2 having occlusion 3. Injuring a bypass vessel may be through a catheter equipped with a cutter or puncturing feature, such as needles 14 of Figures 1 and 2 (paragraph [0041]), cryocatheters or heated catheters (paragraph [0042]).

Referring again to claim 1, the claim also provides delivering an arteriogenic factor to a bypass vessel in a medically effective manner to structurally enlarge an existing blood vessel. Arteriogenic factors may include a chemical, drug, protein, or gene construct. See paragraphs [0025]-[0027] and [0029]. Alternatively, the arteriogenic factor may be a physical factor such as a device (e.g., needle). See paragraph [0041]. The arteriogenic factor may be delivered extravascularly (paragraph 34) or intravascularly (paragraph [0037]).

Referring to claim 2, claim 2 describes the method of claim 1 wherein the delivery comprises providing an arteriogenic factor to the vessel region for a duration ranging from one week to about five weeks. This is described in the application at, for example, paragraph 30 wherein treatments with an immediate induction are described as well as treatments over a predetermined duration of time. Claim 3 describes the method of claim 1 further comprising providing a second delivery of an arteriogenic factor to the vessel region at about 3 to about 10 days after an initial delivering. This is described in the application at paragraph [0030].

Claims 4 and 5 depend from claim 1 and describe a delivery as alternatively advancing the arteriogenic factor from a syringe or a needle catheter to a vessel region. Such delivery is described, for example, with reference to paragraph [0032] (needle catheter) and paragraph [0035] (syringe).

Claim 6 describes the method of claim 1 wherein delivery comprises providing a porous balloon catheter having a porous balloon to accommodate the arteriogenic factor and advancing the arteriogenic factor from the porous balloon to a vessel region via pores of the porous balloon. An embodiment of a porous balloon catheter is described in the application, for example, with reference to Figure 3 and paragraph [0037].

Claim 8 describes the method of claim 1 wherein the arteriogenic factor is a needle catheter and delivery comprises advancing the needle catheter to the vessel region, the needle to puncture the vessel region. This is described in the Application at, for example, paragraph [0041].

Claims 10 and 11 depend from claim 1 and describe delivering the arteriogenic factor including delivering a catheter with a distal portion cooled to between about 0°C and about 10°C or heated to a range from 40°C to about 90°C. Examples of such deliveries are described in the Application at, for example, paragraph [0042].

Independent claim 24 describes a method of structurally enlarging a bypass vessel adjacent to a primary vessel. The method includes injuring a bypass vessel; advancing a distal portion of a catheter to the bypass vessel; delivering an arteriogenic factor in a medically effective manner to the bypass vessel via the catheter; and causing an enlargement to at least a portion of the bypass vessel.

As noted above, with respect to claim 1, the Application describes injuring a bypass vessel at, for example, paragraph [0041]. Figures 1 and 2 of the Application show needle catheter advanced to bypass vessel 7 (bypass vessel 7 relative to primary vessel 2). As described in paragraph [0024], the needle catheter may deliver an arteriogenic factor to act upon and induce arteriogenesis of bypass vessel 7.

Claim 33 depends from claim 24 and describes delivering further comprising providing an arteriogenic factor to the bypass vessel for a duration ranging from about one week to about five weeks. This is described in the Application at, for example, paragraph [0030].

Claim 34 describes the method of claim 24, wherein delivering further comprises providing a second delivery of an arteriogenic factor to a bypass vessel at about 3 to about 10

days after a first delivering of an arteriogenic factor. This is described in the Application, for example, at paragraph [0030].

Claim 35 depends from claim 24 and further describes delivering including providing a syringe to accommodate the arteriogenic factor and advancing the arteriogenic factor from the syringe to a bypass vessel. This is described in the Application at, for example, paragraph [0035].

Claim 36 depends from claim 24 and describes delivering further comprising providing a needle catheter to accommodate the arteriogenic factor and advancing the arteriogenic factor from the needle catheter to a bypass vessel. This is described in the Application at, for example, paragraphs [0032]-[0034].

Finally, claim 37 depends from claim 24 and describes delivering further comprising providing a porous balloon catheter having a porous balloon to accommodate the arteriogenic factor and advancing the arteriogenic factor from the porous balloon to a bypass vessel via the pores of the porous balloon. This is described in the Application at, for example, paragraph [0037] and Figure 3.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection in this appeal are:

1) Whether claims 1, 5-6, 8, 24, 36 and 37 are anticipated under 35 U.S.C. §102(e) over U.S. Patent No. 6,048,332 issued to Duffy (Duffy); and

2) Whether claims 2-4, 10-11 and 33-35 are obvious under 35 U.S.C. §103(a) over Duffy.

VII. ARGUMENT

A. Overview of U.S. Patent No. 6,048,332

U.S. Patent No. 6,048,332 to Duffy (Duffy) discloses systems and methods using a drug delivery catheter that includes a porous balloon mounted onto the distal end of the catheter. See Abstract. The systems and methods may deliver a treatment agent to an inner or luminal surface of a body lumen or deliver a treatment agent that may be carried to other locations within the body to provide treatment to areas larger than or distant from the areas of tissue contact. See col. 4, lines 46-56.

Duffy also describes systems and methods that can be used to introduce a treatment agent following techniques intended to dilate stenotic regions of a body lumen or other techniques to treat localized lesions of a body lumen. See col. 12, lines 5-8. "For example, a stenotic region of a blood vessel 84 can be stretched using the techniques of balloon dilation and can thereupon be treated with the methods and systems described herein. As another example, drug delivery according to these methods can be applied following procedures such as angioplasty, atherotomy, atherectomy and stent placement." Col. 12, lines 18-24.

B. Rejection of Claims

35 U.S.C. §102(e): Rejection of Claims 1, 5-6, 8, 24 & 36-37

The Patent Office rejects claims 1, 5-6, 8, 24 and 36-37 under 35 U.S.C. §102(e) as anticipated by Duffy.

In order to anticipate a claim, the Examiner must show that a single reference teaches each of the elements of that claim. Verdegaal Bros., Inc. v. Union Oil Co. of California, 2 USPQ 2d 1051, 1053 (Fed. Cir.), cert. denied, 631 U.S. 827 (1987). A single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim. Id.

Claim 1 describes a method comprising injuring a vessel region wherein the vessel region comprises a bypass vessel. The bypass vessel is adjacent to a primary vessel leading to a target

area for blood flow. The method also provides delivering an arteriogenic factor to the bypass vessel in a medically effective manner structurally to enlarge an existing blood vessel.

Independent claim 1 is not anticipated by Duffy, because Duffy does not describe injuring a vessel region that comprises a bypass vessel adjacent to a primary vessel leading to a target area for blood flow. Duffy describes introducing a catheter with a porous balloon into a blood vessel. Duffy does not describe introducing its device or delivering a treatment agent into a vessel that comprises a bypass vessel adjacent to a primary vessel leading to a target area of blood flow. Duffy describes systems and methods for use following techniques to dilate a stenotic region of a blood vessel. In this context, Duffy is describing treating the blood vessel containing the stenosis, not a bypass vessel.

Claim 1 is also not anticipated by Duffy, because Duffy does not describe delivering an arteriogenic factor to a bypass vessel. Appellant is unable to find, for example, any discussion in Duffy relating to potential treatment agents or drugs that might be arteriogenic factors or the delivery of arteriogenic factors through the described devices. In dilation cases referenced by Duffy, the stenotic region in a blood vessel may be stretched or dilated by a device, but Duffy does not teach dilation techniques. According to one embodiment, Duffy merely follows such dilation techniques. It may be possible that the inflation of the balloon in the device of Duffy could cause a physical injury to the blood vessel in the treatment described by Duffy (a possible physical arteriogenic factor). However, this is only speculation on Appellant's part and not specifically taught by or does not necessarily flow from the teachings of Duffy.

In the Office Action mailed August 10, 2006, the Patent Office stated "that the delivery of an arteriogenic factor to a vessel region would result in the arteriogenic factor being supplied to the primary vessel and any bypass vessel in the region." See Office Action mailed August 10, 2006, page 2. Such a statement has no basis in the facts before the Patent Office with regard to the application of the cited art. Appellant therefore believes the Patent Office is taking official notice of facts not of record. Official notice, unsupported by documentary evidence, should only be taken by the Patent Office where the fact asserted is well known, or is common knowledge in the art, capable of instant and unquestionable demonstration as being well known. See MPEP 2144.03. To the extent the Patent Office relies on the doctrine of inherency, the Patent Office

must provide a basis in fact or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the prior art. See Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Patent App. & Int. 1990). An example of why the Patent Office's statement is not necessarily true may be seen in Figures 1-3 of the Application where bypass vessels 7 and 8 branch off primary vessel 9. If an arteriogenic factor (either physical, biological or chemical) is delivered to bypass vessel 7 or 8 downstream of the branching-off point from primary vessel 9, it does not necessarily follow that the arteriogenic factor would be supplied to primary vessel 9.

In the Office Action mailed August 10, 2006, the Patent Office also states that "the delivery of an arteriogenic factor would inherently damage the vessel region, even if only minimally." See Office Action, page 4. Again, there is no basis for such a statement. For example, it is entirely possible to deliver an arteriogenic factor into a blood vessel through a delivery mechanism where a delivery device does not touch the luminal surface of the blood vessel where the arteriogenic factor is delivered. One way is inflating a porous balloon (such as the porous balloon of Figure 3 of the Application) to a diameter that is less than a diameter of bypass vessel 7 and introducing the arteriogenic factor through pores 30 of balloon 23. Blood flow around the inflated porous balloon could keep the balloon approximately centered in bypass vessel 7 so that the balloon could not touch the vessel walls.

Referring to the final Office Action mailed August 10, 2006, the Patent Office also states that in all likelihood the vessel region was injured previously "hence the need of the arteriogenic factor of Duffy." See Office Action, page 4. Again, there is no basis in fact for the opinion or conclusion that a vessel region including a bypass vessel is previously injured. Claim 1 is addressing an "injury" or occlusion in a primary vessel through acts directed at a bypass vessel. Such a statement by the Patent Office also misunderstands an object of claim 1. It is appreciated that, in one embodiment, delivery of an arteriogenic factor to a bypass vessel may structurally enlarge the bypass vessel or another vessel thereby allowing blood flow to bypass a primary vessel in route to a target area. Injuring of the bypass vessel along with delivery of an arteriogenic factor will accelerate the structural enlargement of the bypass vessel or another vessel. Thus, in one aspect, a bypass vessel is injured to accelerate arteriogenisis.

Finally, the Patent Office states that "[t]he patent by Duffy therefore shows the same structure as is claimed, and should be expected to achieve the same results." See Office Action mailed August 10, 2006, page 4. Appellant notes that the pending claims are directed to a method and not a structure, therefore any similarity in structure between what is described in the Application and Duffy is irrelevant.

Claims 5-6 and 8 depend from claim 1 and therefore contain all the limitations of the claim. For at least the reasons stated with respect to claim 1, claims 5-6 and 8 are not anticipated by Duffy.

Independent claim 24 describes a method of structurally enlarging a bypass vessel adjacent to a primary vessel. The method comprises: injuring a bypass vessel; advancing a distal portion of a catheter to the bypass vessel; delivering an arteriogenic factor to the bypass vessel via the catheter; and causing an enlargement to at least a portion of the bypass vessel.

As noted above, with respect to claim 1, Duffy does not describe injuring a bypass vessel adjacent to a primary vessel; advancing a distal portion of a catheter to the bypass vessel; or delivering an arteriogenic factor to the bypass vessel. Further, Duffy does not describe causing an enlargement to at least a portion of the bypass vessel.

Claims 36 and 37 depend from claim 24 and contains all the limitations of that claim. For at least the reasons stated with respect to claim 24, claims 36 and 37 are not anticipated by Duffy.

Appellant respectfully requests that the Patent Office withdraw the rejection to claims 1, 5-6, 8, 24 and 36-37 under 35 U.S.C. §102(e).

35 U.S.C. 103(a): Rejection of Claims 2-4, 10-11 & 34-35

To establish a *prima facie* case of obviousness, the relied upon references must teach or suggest every limitation of the claim such that the invention as a whole would have been obvious at the time the invention was made to one skilled in the art. In re Keller, 208 USPQ 871, 881 (C.C.P.A. 1981). An obviousness inquiry assesses "the differences between the subject matter sought to be patented and the prior art" to ascertain whether "the subject matter as a whole would

have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. §103(a) (1994). The determination of obviousness requires an evaluation of: (1) the scope and content of the prior art; (2) the level of skill in the pertinent art; and (3) the differences between the claimed invention and the prior art. In re Dembiczak, 50 USPQ2d 1614, 1616 (Fed. Cir. 1991).

To be deemed to have been obvious, the claimed subject matter, considered as a whole, must be analyzed as of the time the invention was made, not in view of the hindsight provided by the disclosure set forth in the patent. W.L. Gore & Associates Inc. v. Garlock, Inc., 220 USPQ 303, 313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Where the prior art gives reason or motivation to make the claimed invention, the burden and opportunity then falls on an applicant to rebut that *prima facie* case. Such rebuttal or argument can consist of any other argument or presentation of evidence that is pertinent. In re Dillon, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (en banc), cert. denied, 500 U.S. 904 (1991). After evidence or argument is submitted by the applicant in response to an obviousness rejection, patentability is determined on the totality of the record, with due consideration to the persuasiveness of the argument. In re Oetiker, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

The Patent Office rejects claims 2-4, 10-11 and 34-35 under 35 U.S.C. §103(a) as obvious over Duffy. Claims 2-4 and 10-11 depend from claim 1 and therefore contain all the limitations of that claim. For the reasons stated above with respect to independent claim 1, claims 2-4 and 10-11 are not obvious over Duffy. Duffy fails to teach or provide any motivation for injuring a vessel region comprising a bypass vessel adjacent to a primary vessel or delivering an arteriogenic factor to the bypass vessel. With regard to "injured" vessels, at best Duffy teaches treating a vessel that contained a stenotic region. "For example, a stenotic region of a blood vessel 84 can be stretched using the techniques of balloon dilation and can be thereupon treated with the methods and systems described herein." Col. 12, lines 18-21. It is clear from the quoted language that the vessel with the stenotic region is receiving the treatment, not a bypass vessel.

Duffy also fails to teach or provide motivation for delivering an arteriogenic factor to a bypass vessel. From the language quoted above of Duffy, the vessel receiving treatment is the

vessel with the stenotic region. It is not clear how an arteriogenic factor (having a property to increase the size of a blood vessel) administered to a blood vessel containing a stenosis will treat that vessel. As noted in the teachings of the Application, not Duffy, one way to treat myocardial tissue that has seen a reduction of blood flow due to a stenosis in a primary vessel is to increase the size of one or more bypass vessels that may bypass the primary vessel in providing blood to the myocardial tissue. It is this bypass vessel(s) that would benefit from the arteriogenic factor.

In addition, with respect to claim 2, Duffy does not teach or provide any motivation for delivering an arteriogenic factor for a duration ranging from about one week to about five weeks. With respect to claim 3, Duffy does not teach or provide any motivation for providing a second delivery of an arteriogenic factor to a vessel region at about three to about ten days following a delivery. With respect to claim 4, Duffy does not teach or provide any motivation for advancing an arteriogenic factor from a syringe to a vessel region. With respect to claim 10, Duffy does not teach or provide any motivation for delivering an arteriogenic factor by a catheter with a distal portion cooled to about 0°C and about 10°C. With respect to claim 11, Duffy does not teach or provide any motivation for delivering an arteriogenic factor by a catheter with a distal portion heated to a range from about 40°C to about 90°C.

Claims 33-35 depend from claim 24 and therefore contain all the limitations of that claim. For the reasons stated with respect to claim 24, claims 33-35 are not obvious over Duffy. Duffy does not teach or provide any motivation for injuring a bypass vessel adjacent to a primary vessel; advancing a distal portion of a catheter to the bypass vessel; or delivering an arteriogenic factor to the bypass vessel.

In addition, with respect to claim 33, Duffy also does not teach or provide any motivation for providing an arteriogenic factor to a bypass vessel for a duration from about one week to about five weeks. With respect to claim 34, Duffy does not teach or provide any motivation for providing a second delivery of an arteriogenic factor to a bypass vessel at about 3 to about 10 days after a delivery of an arteriogenic factor. With respect to claim 35, Duffy also does not teach or provide any motivation for advancing an arteriogenic factor from a syringe to a bypass vessel.

For the above stated reasons, Appellant respectfully requests that the Patent Office withdraw the rejection to claims 2-4, 10-11 and 34-35 under 35 U.S.C. §103(a).

In view of the foregoing, it is believed that all claims now pending (1) are in proper form, (2) are neither obvious nor anticipated by the relied upon art of record, and (3) are in condition for allowance. A Notice of Allowance is earnestly solicited at the earliest possible date. If the Patent Office believes that a telephone conference would be useful in moving the application forward to allowance, the Patent Office is encouraged to contact the undersigned at (310) 207-3800.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly, extension of time fees.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR, & ZAFMAN LLP

Dated: 1/8/07

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CERTIFICATE OF TRANSMISSION
I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

Nedy Calderon 1/8/07
Nedy Calderon Date

VII. CLAIMS APPENDIX

The claims involved in this Appeal are as follows:

1. (Previously Presented) A method comprising:

injuring a vessel region, said vessel region comprising a bypass vessel adjacent to a primary vessel leading to a target area for blood flow, said primary vessel having an occlusion to blood flow; and

delivering an arteriogenic factor to said bypass vessel in a medically effective manner to structurally enlarge an existing blood vessel.

2. (Original) The method of claim 1 wherein said delivery comprises providing said arteriogenic factor to said vessel region for a duration ranging from about one week to about five weeks.

3. (Original) The method of claim 1 further comprising providing a second delivery of said arteriogenic factor to said vessel region at about 3 to about 10 days after said delivering.

4. (Previously Presented) The method of claim 1 wherein said delivery comprises:

providing a syringe to accommodate said arteriogenic factor; and

advancing said arteriogenic factor from said syringe to said vessel region.

5. (Original) The method of claim 1 wherein said delivery comprises:

providing a needle catheter to accommodate said arteriogenic factor; and

advancing said arteriogenic factor from said needle catheter to said vessel region.

6. (Original) The method of claim 1 wherein said delivery comprises:

providing a porous balloon catheter having a porous balloon to accommodate said arteriogenic factor; and

advancing said arteriogenic factor from said porous balloon to said vessel region via pores of said porous balloon.

7. (Canceled).

8. (Previously Presented) The method of claim 1 wherein said arteriogenic factor is a needle catheter, said delivery comprising advancing a needle of said needle catheter to said vessel region, said needle to puncture said vessel region.

9. (Canceled).

10. (Previously Presented) The method of claim 1 wherein delivering said arteriogenic factor includes delivering a catheter with a distal portion cooled to between about 0° C and about 10 ° C.

11. (Previously Presented) The method of claim 1 wherein delivering said arteriogenic factor includes delivering a catheter with a distal portion heated to a range from about 40° C to about 90°C.

12.-23. (Canceled)

24. (Previously Presented) A method of structurally enlarging a bypass vessel adjacent to a primary vessel, said method comprising:

injuring said bypass vessel;

advancing a distal portion of a catheter to said bypass vessel;

delivering an arteriogenic factor in a medically effective manner to said bypass vessel via said catheter; and

causing an enlargement to at least a portion of the bypass vessel.

25.-32. (Canceled)

33. (Previously Presented) The method of claim 24 wherein delivering further comprises providing said arteriogenic factor to said bypass vessel for a duration ranging from about one week to about five weeks.

34. (Previously Presented) The method of claim 24 wherein delivering further comprises providing a second delivery of said arteriogenic factor to said bypass vessel at about 3 to about 10 days after a first delivering of said arteriogenic factor.

35. (Previously Presented) The method of claim 24 wherein delivering further comprises:
providing a syringe to accommodate said arteriogenic factor; and
advancing said arteriogenic factor from said syringe to said bypass vessel.

36. (Previously Presented) The method of claim 24 wherein delivering further comprises:
providing a needle catheter to accommodate said arteriogenic factor; and
advancing said arteriogenic factor from said needle catheter to said bypass vessel.

37. (Previously Presented) The method of claim 24 wherein delivering further comprises:
providing a porous balloon catheter having a porous balloon to accommodate said arteriogenic factor; and
advancing said arteriogenic factor from said porous balloon to said bypass vessel via pores of said porous balloon.

X. EVIDENCE APPENDIX

No evidence is submitted with this appeal.

XI. RELATED PROCEEDINGS APPENDIX

No related proceedings exist.